Proposed Amendments to 02 NCAC 09B .0116
To be published in the NC Register 12/17/12

TEXT OF PROPOSED RULES:

02 NCAC 09B .0116 ADOPTIONS BY REFERENCE

(a) The Board incorporates by reference, including subsequent amendments and editions, "Official Methods of Analysis of AOAC," published by the Association of Official Analytical Chemists. Copies of this document may be obtained from the Association of Official Analytical Chemists International, Department 0742, 1970 Chain Bridge Road, McLean, VA 22109-0742, at a cost of six hundred thirty dollars ($630.00).

(b) The Board incorporates by reference, including subsequent amendments and editions, "U.S. Pharmacopeia National Formulary USP XXXIII-NFXXVIII" and supplements, published by the U.S. Pharmacopeial Convention, Inc. Copies of this document may be obtained from The United States Pharmacopeial Convention, Inc., Attention: Customer Service, 12601 Twinbrook Parkway, Rockville, MD 20852, at a cost of ~~eight hundred dollars ($800).~~ eight-hundred fifty dollars ($850.00).

(c) The Board incorporates by reference, including subsequent amendments and editions, "ASTM Standards on Engine Coolants," published by ~~the American Society for Testing Materials~~ ASTM International. Copies of this document may be obtained from ~~the American Society for Testing Materials~~ ASTM International, 100 Bar Harbor Drive, West Conshohocken, PA 19428-2959, at a cost of one ~~hundred eighty-six dollars ($186.00).~~ two hundred eleven dollars ($211.00).

(d) The Board incorporates by reference, including subsequent amendments and editions, "EPA Manual of Chemical Methods for Pesticides and Devices" and supplements, published by AOAC. Copies of this document may be obtained online from ~~from~~ the Environmental Protection Agency National Service Center for Environmental Publications at http://nepis.epa.gov/EXE/ZyPURL.cgi?Dockey=2000YS3Y.txt.

(e) The Board incorporates by reference, including subsequent amendments and editions, "Pesticide Analytical Manual," Volumes I and II, published by the United States Department of Health and Human Services, Food and Drug Administration. Copies of this document may be obtained online at http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/PesticideAnalysisManualPAM/default.htm.

(f) The Board incorporates by reference, including subsequent amendments and editions, "FDA Compliance Policy Guides," published by the United States Department of Health and Human Services, Food and Drug Administration. Copies of this document may be obtained online at ~~http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManuals/default.htm~~ http://www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/default.htm or from the State Information Branch (HFC-151), Division of Federal-State Relations, US Food and Drug Administration, 5600 Fishers Lane, Room 12-07, Rockville, MD 20857.

(g) The Board incorporates by reference, including subsequent amendments and editions, "Bergey's Manual of Determinative Bacteriology," Lippincott, Williams & Wilkins Company, Baltimore. Copies of this document may be obtained from the Lippincott, Williams & Wilkins Company, P.O. Box 1620, Hagerstown, MD 21741 at a cost of ~~one hundred ten dollars ($110.00).~~ one hundred thirty-seven dollars and ninety-nine cents ($137.99).

(h) The Board incorporates by reference, including subsequent amendments and editions, "Microbiology Laboratory Guidebook," published by the United States Department of Agriculture, Food Safety and Inspection Service, Washington, DC. Copies of this document may be obtained online from http://www.fsis.usda.gov/science/microbiological_Lab_Guidebook/ at no charge.

(i) The Board incorporates by reference, including subsequent amendments and editions, "FDA Bacteriological Analytical Manual," published by the United States Department ~~o f~~ of Health and Human Services, Food and Drug Administration. Copies of this

document may be obtained online at http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/default.htm.

(j) The Board incorporates by reference, including subsequent amendments and editions, "Standard Methods for the Examination of Dairy Products," published by the American Public Health Association. Copies of this document may be obtained from the American Public Health Association Publication Sales, P.O. Box 933019, Atlanta, GA at a cost of eighty-five dollars ($85.00).

(k) The Board incorporates by reference, including subsequent amendments and editions, "Compendium of Methods for the Microbiological Examination of Foods," published by the American Public Health Association. Copies of this document may be obtained from the American Public Health Association Publication Sales, P.O. Box 933019, Atlanta, GA at a cost of one hundred fifty dollars ($150.00).

(l) The Board incorporates by reference, including subsequent amendments and editions, "Bergey's Manual of Systematic Bacteriology," Springer Publishing, New York, NY. Copies of this document may be obtained from Springer Publishing, 233 Spring Street, New York, NY, 10013 at a cost of ~~one hundred thirty-nine dollars ($139.00).~~ one hundred fifty-nine dollars ($159.00).

(m) The Board incorporates by reference, including subsequent amendments and editions, "Manual of Clinical Microbiology," published by the American Society for Microbiology. Copies of this document may be obtained from the American Society for Microbiology Press, PO Box 605, Herndon, VA 22070, at a cost of ~~two-hundred nine dollars and ninety-five cents ($209.95).~~ two hundred sixty-five dollars and ninety-five cents ($269.95).

(n) The Board incorporates by reference, including subsequent amendments and editions, "Standard Methods for the Examination of Water and Waste Water," published by American Public Health Association, American Water Works Association, and Water Pollution Control Federation. Copies of this document may be obtained from the American Public Health Association Publication Sales, P.O. Box 933019, Atlanta, GA at a cost of ~~two hundred fifty dollars ($250.00).~~ two hundred ninety-five dollars ($295.00).

(o) The Board incorporates by reference, including subsequent amendments and editions, the following parts or sections of the Code of Federal Regulations, Title 21, Chapter I, as promulgated by the Commissioner of the Food and Drug Administration under the authority of the Federal Food, Drug, and Cosmetic Act:

	Part or Section	Subject of Part or Section
(1)	1.1	General
(2)	1.3	Labeling - Definitions
(3)	1.20	Presence of Mandatory Label Information
(4)	1.21	Failure to Reveal Material Facts
(5)	1.24	Exemptions from Required Label Statements
(6)	1.326	Persons Subject to this Subpart
(7)	1.327	Exclusions from All or Part of Regulations in this Subpart
(8)	1.328	Definitions for this Subpart
(9)	1.329	Other Statutory Provisions and Regulations
(10)	1.330	Use of Existing Records
(11)	1.337	Information Non-transporters Must Establish and Maintain to Identify the Nontransporter and Transporter Immediate Previous Sources of Food
(12)	1.345	Information Non-transporters Must Establish and Maintain to Identify the Nontransporter and Transporter Immediate Subsequent Recipients of Food
(13)	1.352	Information Transporters Must Establish and Maintain
(14)	1.360	Record Retention Requirements
(15)	1.361	Record Availability Requirements

(16) 1.362 Records Excluded from this Subpart

(17) 1.363 Consequences of Failing to Establish, Maintain, or Make Available Records

(18) 1.368 Compliance Dates

~~(6)~~(19) 2.25 Grain Seed Treated with Poisonous Substances; Color Identification to Prevent Adulteration of Human and Animal Food

~~(7)~~(20) 2.35 Use of Secondhand Containers for the Shipment or Storage of Food and Animal Feed

(21) 7.1 Scope

(22) 7.3 Definition

~~(8)~~(23) 7.12 Guaranty

~~(9)~~(24) 7.13 Suggested Forms of Guaranty

(25) 7.40 Recall Policy

(26) 7.41 Health Hazard Evaluation and Classification

(27) 7.42 Recall Strategy

(28) 7.45 Food and Drug Administration - Requested Recall

(29) 7.46 Firm-initiated Recall

(30) 7.49 Recall Communications

(31) 7.50 Public Notification of Recall

(32) 7.53 Recall Status Reports

(33) 7.55 Termination of Recall

(34) 7.59 General Industry Guidance

~~(10)~~(35) 70 Color Additives

~~(11)~~(36) 73 Listing of Color Additives Exempt from Certification

~~(12)~~(37) 74 Listing of Color Additives Subject to Certification

~~(13)~~(38) 81 General Specifications and General Restrictions for Provisioned Color Additives for Use in Foods, Drugs and Cosmetics

~~(14)~~(39) 82 Listing of Certified Provisionally Listed Colors and Specifications

~~(15)~~(40) 100 General

~~(16)~~(41) 101 Food Labeling

~~(17)~~(42) 102 Common or Usual Name for Nonstandardized Foods

~~(18)~~(43) 104 Nutritional Quality Guidelines for Foods

~~(19)~~(44) 105 Foods for Special Dietary Use

~~(20)~~(45) 106 Infant Formula Quality Control Procedures

~~(21)~~(46) 107 Infant Formula

~~(22)~~(47) 108 Emergency Permit Control

~~(23)~~(48) 109 Unavoidable Contaminants in Food for Human Consumption and Food-Packaging Material

~~(24)~~(49) 110 Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding Human Food

(50) 111 Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements

~~(25)~~(51) 113 Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers

~~(26)~~(52) 114 Acidified Foods

(53) 115 Shell Eggs

(54) 118 Production, Storage, and Transportation of Shell Eggs

~~(27)~~(55) 120 Hazard Analysis and Critical Control Point (HACCP) Systems

~~(28)~~(56) 123 Frozen Raw Breaded Shrimp

~~(29)~~(57) 129 Processing and Bottling of Bottled Drinking Water (Except as amended by 02 NCAC 09C .0700 - Bottled Water)

~~(30)~~(58) 130 Food Standards: General

~~(31)~~(59) 131 Milk and Cream

~~(32)~~(60) 133 Cheeses and Related Cheese Products

~~(33)~~(61) 135 Frozen Desserts

~~(34)~~(62) 136 Bakery Products

~~(35)~~(63) 137 Cereal Flours and Related Products

~~(36)~~(64) 139 Macaroni and Noodle Products

~~(37)~~(65) 145 Canned Fruits

~~(38)~~(66) 146 Canned Fruit Juices

~~(39)~~(67) 150 Fruit Butters, Jellies, Preserves, and Related Products

~~(40)~~(68) 152 Fruit Pies

~~(41)~~(69) 155 Canned Vegetables

~~(42)~~(70) 156 Vegetable Juices

~~(43)~~(71) 158 Frozen Vegetables

~~(44)~~(72) 160 Eggs and Egg Products

~~(45)~~(73) 161 Fish and Shellfish (Except Section 161.30 and 161.130 through 161.145)

~~(46)~~(74) 163 Cacao Products

~~(47)~~(75) 164 Tree Nut and Peanut Products

~~(48)~~(76) 165 Beverages

~~(49)~~(77) 166 Margarine

~~(50)~~(78) 168 Sweeteners and Table Syrups

~~(51)~~(79) 169 Food Dressings and Flavorings

~~(52)~~(80) 170 Food Additives

~~(53)~~(81) 172 Food Additives Permitted for Direct Addition to Food for Human Consumption

~~(54)~~(82) 173 Secondary Direct Food Additives Permitted in Food for Human Consumption

~~(55)~~(83) 174 Indirect Food Additives: General

~~(56)~~(84) 175 Indirect Food Additives: Adhesive Coatings and Components

~~(57)~~(85) 176 Indirect Food Additives: Paper and Paperboard Components

~~(58)~~(86) 177 Indirect Food Additives: Polymers

~~(59)~~(87) 178 Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

~~(60)~~(88) 179 Irradiation in the Production, Processing and Handling of Food

~~(61)~~(89) 180 Food Additives Permitted in Food on an Interim Basis or in Contact with Food Pending Additional Study

~~(62)~~(90) 181 Prior-Sanctioned Food Ingredients

~~(63)~~(91) 182 Substances Generally Recognized as Safe

~~(64)~~(92) 184 Direct Food Substances Affirmed as Generally Recognized as Safe

~~(65)~~(93) 186 Indirect Food Substances Affirmed as Generally Recognized as Safe

~~(66)~~(94) 189 Substances Prohibited from Use in Human Food

(95) 190 Dietary Supplements

~~(67)~~(96) 200 General

~~(68)~~(97) 201 Labeling

~~(69)~~(98) 202 Prescription Drug Advertising

~~(70)~~(99) 210 Current Good Manufacturing Practices in Manufacturing, Processing, Packing or Holding of Drugs; General

~~(71)~~(100)211 Current Good Manufacturing Practice for Finished Pharmaceuticals

~~(72)~~(101)225 Current Good Manufacturing Practice for Medicated Feeds

~~(73)~~(102)226 Current Good Manufacturing Practice for Medicated Premixes

~~(74)~~(103)250 Special Requirements for Specific Human Drugs

~~(75)~~(104)290 Controlled Drugs

~~(76)~~(105)299 Drugs; Official Names and Established Names

~~(77)~~(106)300 General

~~(78)~~(107)310 New Drugs

~~(79)~~(108)312 New Drugs for Investigational Use

~~(80)~~(109)314 New Drug Applications

~~(81)~~(110)320 Bioavailability and Bioequivalence Requirements

~~(82)~~(111)330 Over-the-Counter (OTC) Human Drugs Which Are Generally Recognized as Safe and Effective and Not Misbranded

~~(83)~~(112)331 Antacid Products for Over-the-Counter (OTC) Human Use

~~(84)~~(113)332 Antiflatulent Products for Over-the-Counter Human Use

~~(85)~~(114)361 Prescription Drugs for Human Use Generally Recognized as Safe and Effective and Not Misbranded: Drugs Used in Research

~~(86)~~(115)369 Interpretive Statements Re: Warnings on Drugs and Devices for Over-the-Counter Sale

~~(87)~~(116)809 In Vitro Diagnostic Products for Human Use

~~(88)~~(117)812 Investigational Device Exemptions

~~(89)~~(118)820 ~~Good Manufacturing Practices for Medical Devices: General~~ Quality System Regulation

~~(90)~~(119)860 Medical Device Classification Procedures

~~(91)~~(120)861 Procedures for Performance Standards Development

~~(92)~~(121)870 Cardiovascular Devices

~~(93)~~(122)882 Neurological Devices

~~(94)~~(123)884 Obstetrical and Gynecological Devices

~~(95)~~(124)895 Banned Devices

~~(96)~~(125)500 General

~~(97)~~(126)501 Animal Food Labeling

~~(98)~~(127)502 Common or Usual Names for Nonstandardized Animal Foods

~~(99)~~(128)509 Unavoidable Contaminants in Animal Food and Food-Packaging Material

~~(100)~~(129)510 New Animal Drugs

~~(101)~~(130)511 New Animal Drugs for Investigational Use

~~(102)~~(131)514 New Animal Drug Applications

~~(103)~~(132)520 Oral Dosage Form New Animal Drugs Not Subject to Certification

~~(104)~~(133)522 Implantation of Injectable Dosage Form New Animal Drugs Not Subject to Certification

~~(105)~~(134)524 Ophthalmic and Topical Dosage Form New Animal Drugs Not Subject to Certification

~~(106)~~(135)526 Intramammary Dosage Forms Not Subject to Certification

~~(107)~~(136)529 Certain Other Dosage Form New Animal Drugs Not Subject to Certification

~~(108)~~(137)556 Tolerances for Residues of New Animal Drugs in Food

~~(109)~~(138)558 New Animal Drugs for Use in Animal Feeds

~~(110)~~(139)570 Food Additives

~~(111)~~(140)573 Food Additives Permitted in Feed and Drinking Water of Animals

~~(112)~~(141)582 Substances Generally Recognized as Safe

~~(113)~~(142)584 Food Substances Affirmed as Generally Recognized as Safe in Feed and Drinking Water of Animals

~~(114)~~(143)589 Substances Prohibited from Use in Animal Food or Feed

~~(115)~~(144)700 General

~~(116)~~(145)701 Cosmetic Labeling

~~(117)~~(146)720 Voluntary Filing of Cosmetic Product Ingredient and Cosmetic Raw Material Composition Statements

~~(118)~~(147)740 Cosmetic Product Warning Statements

~~(119) 111 Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements~~

~~(120) 190 Dietary Supplements~~

~~(121) 7.1 Scope~~

~~(122) 7.3 Definition~~

~~(123) 7.40 Recall Policy~~

~~(124) 7.41 Health Hazard Evaluation and Classification~~

~~(125) 7.42 Recall Strategy~~

~~(126) 7.45 Food and Drug Administration-Requested Recall~~

~~(127) 7.46 Firm-initiated Recall~~

~~(128) 7.49 Recall Communications~~

~~(129) 7.50 Public Notification of Recall~~

~~(130) 7.53 Recall Status Reports~~

~~(131) 7.55 Termination of Recall~~

~~(132) 7.59 General Industry Guidance~~

Copies of the Code of Federal Regulations may be obtained at no cost by accessing the website of the U.S. Government Printing Office at http://www.gpoaccess.gov/cfr/index.html.

(p) The Board incorporates by reference, including subsequent amendments and editions, "Tolerances and Exemptions from Tolerances for Pesticide Chemicals in or on Raw Agricultural Commodities," 40 C.F.R. Part 180. Copies of the Code of Federal Regulations may be obtained from the Superintendent of Documents, Government Printing Office, Washington, DC 20402, at a cost of fifty-six dollars ($56.00).

(q) The Board incorporates by reference, including subsequent amendments and editions, "Definitions and Standards of Identity or Composition for Meats, Meat By-products, and Meat Food Products," 9 C.F.R. Part 319. Copies of the Code of Federal Regulations may be obtained from the Superintendent of Documents, Government Printing Office, Washington, DC 20402, at a cost of sixty-four dollars ($64.00).

(r) The Board incorporates by reference, including subsequent amendments and editions, "Definitions and Standards of Identity or Composition for Poultry and Poultry Products," 9 C.F.R. Sections 381.155 through 381.170. Copies of the Code of Federal

Regulations may be obtained from the Superintendent of Documents, Government Printing Office, Washington, DC 20402, at a cost of sixty-four dollars ($64.00).

(s) The Board incorporates by reference, including subsequent amendments and editions, Title 9, Part 317.2(1) of the Code of Federal Regulations. Copies of Title 9 of the Code of Federal Regulations may be obtained from the Superintendent of Documents, Government Printing Office, Washington, DC 20402, at a cost of sixty-four dollars ($64.00).

(t) The Board incorporates by reference, including subsequent amendments and editions, Title 9, Part 381.125(b) of the Code of Federal Regulations. Copies of Title 9 of the Code of Federal Regulations may be obtained from the Superintendent of Documents, Government Printing Office, Washington, DC 20402, at a cost of sixty-four dollars ($64.00).

(u) The Board incorporates by reference, including subsequent amendments and editions, a document entitled, "Fresh Air '2000' - A Look At FDA's Medical Gas Requirements," published by the United States Department of Health and Human Services, Food and Drug Administration.. A copy of this material may be obtained at no cost from the Food and Drug Protection Division of the North Carolina Department of Agriculture and Consumer Services.

(v) The Board incorporates by reference the definition of "dietary supplement" found at 21 USC 321 (ff).

History Note: *Authority G.S. 106-139; 106-245.16; 106-245.22; 106-245.32; 106-267; ~~106-267.2~~*
Eff. December 14, 1981;
Amended Eff. January 1, 2011; June 1, 2004; April 1, 2003; June 1, 1995; April 1, 1992; June 1, 1988; October 1, 1987.

EXPLANATION/REASON FOR PROPSED RULES:

Adoption by reference of these rules will enhance the Department's ability to conduct investigations under G.S. 106-140(a) in a manner consistent with federal standards, including the Manufactured Food Regulatory Program Standards. They also harmonize existing state regulations with federal law in conformity with federal standards and resolve interpretational tension between existing state regulation and the pre-emptive federal regulation. They also support the implementation of a more efficient egg inspection program under the NC Egg Law by harmonizing state regulations with already operative federal requirements.

INSTRUCTIONS ON HOW AND WHERE TO SUBMIT COMMENTS ON THE PROPOSED RULES:

Any person may object to the proposed rules by submitting a written statement of objection(s) to David S. McLeod, Secretary, NC Board of Agriculture, 1001 Mail Service Center, Raleigh NC 27699-1001.

Any person wishing to submit comments on the proposed rules may do so by submitting written comments to David S. McLeod, Secretary, NC Board of Agriculture, 1001 Mail Service Center, Raleigh, NC 27699-1001.

The Comment period ends 2/15/13.